AP

09/

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

HOLLY D KOZLOWSKI
DINSMORE & SHOHL
1900 CHEMED CENTER
255 EAST FIFTH STREET
CINCINNATI OH 45202

NAMED INVENTOR	ATTORNEY DOCKET NO.
A	10806-65
EXAMINER	
PAK, M	
ART UNIT	PAPER NUMBER
1646	12

MAILED: 03/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

PTO-90C (Rev. 2/95)

*U.S. GPO: 2000-473-000/44602

Office Action Summary

Application No.	Applicant(s)
09/143,828	Berkenstam et al.
Examiner	**Group Art Unit**
Michael Pak	1646

☒ Responsive to communication(s) filed on *Dec 7, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-23 and 29-41* is/are pending in the application.

Of the above, claim(s) *10-12, 18-23, 29-31, and 34-41* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-9, 13-17, 32, and 33* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that claims 1-9, 13-17, and 32-33 are generic and the Group I and II are classified in the same class/subclass. This is not found persuasive because Group I and II are directed to distinct inventions where VDRRg and VDRRg2 are structurally different compounds.

The requirement is still deemed proper and is therefore made final.

2. The preliminary amendments filed 30 October 1998 (Paper No. 6) and 21 October 1999 (Paper No. 8) have been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-9, 13-17, and 32-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are directed to a nucleic acid molecule encoding human VDRRg1 and vectors comprising the nucleic acid molecule, cells comprising the vectors, and method of making the protein. However, human VDRRg1 disclosed in the specification is an orphan receptor whose ligand and functional cellular signaling is not known. The specification as filed does not disclose or provide evidence that points to a property of the claimed receptor such that another non-asserted utility would be well established. Since the function of the protein is not known because the receptor signaling is not known, the method of using the protein lacks well established utility. The specification on page 1 disclose the asserted utility of using the polypeptide in identifying potential drug targets for therapeutic invention of common disease. However, there is no nexus between the unknown properties of the receptor and the treatment of the diseases. Thus, the treatment of the disease lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The claimed method using the orphan receptor does not have well established utility because different ligands would have

different functions and the skilled artisan would have to determine the function of the orphan receptor. The claimed polypeptides do not have substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The claims directed to vectors, host cells, and the process of expressing the protein do not have utility because the nucleic acid without utility is needed to practice the inventions.

Claims 1-9, 13-17, and 32-33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35

U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9, 13-17, and 32-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9, 13-17, and 32-33 encompass alleles whose metes and bounds ambiguous because no specific structural limitations are provided. Claims encompass sequence similarity with hVDR or xONR1 domains whose metes and bounds are not clear.

6. Claims 1-9, 13-17, and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims encompass the DNA or vectors and cells comprising the DNA encoding a variant protein which is naturally occurring but not disclosed in the specification nor to one of skilled in the art. Claimed DNA encoding protein variants encompass a large

genus of nuclear receptors which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring receptor is not known. The essential feature of the claimed invention is DNA encoding an orphan receptor whose function is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the genus of orphan receptors structure cannot be envisioned.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1-9, 13-17, and 32-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Kausch et al.(A).

Kausch et al. disclose the isolation of chromosome (column 5). The cell source are human cells (column 6, lines 5-15).

Many chromosomes can be sorted at once(column 9, lines 29-43). Large amounts of pure chromosomes and DNA of the chromosomes is isolated (column 10, lines 22-25). Cells transfected with chromosomal DNA is disclosed (column 10, lines 22-25).

Claims 1-9, 13-17, and 32-33 encompass chromosomal DNA because the claims encompass polynucleotide sequence comprising the polynucleotide sequence encoding a polypeptide with SEQ ID NO:2. The isolated and purified chromosomes comprise the polynucleotide sequence encoding a polypeptide with SEQ ID NO:2. Chromosomal DNA inherently are operably linked to an expression control sequences. Chromosomal DNA inherently comprises heterologous sequence because it undergoes recombination.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
18 February 2001